## REMARKS/ARGUMENTS

Claims 1-14 and 16-28 are pending in the above-identified application. Claims 1, 6, and 12 are amended as set forth in detail below. Support for these amendments are identified in the following remarks. No new matter is added by these amendments. Applicants reserve the right to pursue claims of original scope in a related, co-pending application. Examination and reconsideration of all pending claims are respectfully requested.

### Elections/Restrictions

The Examiner asserts that claims 26-28 are directed to an invention that is patentably distinct from the originally claimed invention and has withdrawn these claims from consideration. As stated by the Examiner, claims 26-28 relate to the originally claimed invention as combination/subcombination, the original invention being drawn to an immunoassay comprising the polypeptide of SEQ ID NO:3, and claims 26-28 being drawn to an immunoassay comprising the polypeptide of SEQ ID NO:3 and two HIV envelope proteins. The Examiner further states that the originally claimed invention has been constructively elected under 37 CFR § 1.142(b) and MPEP § 821.03. On this basis, the Examiner has subjected new claims 26-28 to restriction.

In accordance with 37 CFR § 1.145 and MPEP § 821.03, Applicants respectfully request reconsideration of the present restriction under 37 CFR § 1.143. According to the MPEP, where claims can be examined together without undue burden, the Examiner must examine the claims on the merits even though they are directed to independent or distinct inventions.[1] In establishing that an "undue burden" would exist for co-examination of claims, the Examiner must show that examination of the claims would involve substantially different prior art searches, making the co-examination burdensome.[2] Applicants submit that the originally claimed invention and the inventions recited in claims 26-28 can readily be searched

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[1] *See* MPEP § 803.
[2] *See* MPEP § 803.

without undue burden. Therefore, Applicants respectfully request withdrawal of the present restriction and rejoinder of claims 26-28.

**Oath/Declaration**

The Examiner, referring to "alterations to the original specification which have not been initialed and/or dated," continues to state that a new oath under 37 CFR § 1.67(a) is required. The Examiner states that this requirement was maintained in the Final Rejection mailed May 19, 2004, and was not waived in the Advisory Action mailed December 29, 2004.

In the Final Rejection of May 19, 2004, the Examiner's stated basis for maintaining the requirement for a new oath was that "the substitute specification has been denied entry."[3] Because the substitute specification, lacking the aforementioned "alterations," was approved for entry by the Examiner in the Advisory Action mailed December 29, 2004, the Examiner's stated basis for maintaining the requirement for a new oath was also overcome. Accordingly, withdrawal of the present objection is respectfully requested.

**Rejections under 35 U.S.C. § 112, second paragraph**

Claims 1-12

Claims 1-12 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. The Examiner contends that independent claims 1 and 12 omit an "essential step" because these claims, drawn to a method for determining the presence of HIV in a body fluid, do not recite "the step of taking a sample of body fluid."

Applicants respectfully disagree with the Examiner's position regarding the recitation of "essential matter" in the pending claims under 35 U.S.C. § 112, second paragraph. First, according to the MPEP, "essential elements" of an invention are those defined as such in

[3] Office Action dated May 19, 2004, at page 2.

the specification or from other statements of record.[4] Here, the Examiner has not identified any statements in the specification or otherwise of record to support the contention that an essential step has been omitted.

Further, Applicants note that the MPEP does not list omission of an essential element as a ground for rejection under 35 U.S.C. § 112, second paragraph.[5] The MPEP states that a "claim which omits matter disclosed to be essential to the invention as described in the specification or other statements of record may be rejected under 35 U.S.C. § 112, first paragraph, as not enabling," while a "claim which fails to interrelate essential elements of the invention as defined by applicant(s) in the specification may be rejected under 35 U.S.C. § 112, second paragraph."[6] In the present case, no contention has been set forth by the Examiner regarding the interrelation of essential elements as defined by Applicants.

For at least the reasons above, Applicants respectfully request reconsideration of the present rejection. In the event that the rejection is maintained, Applicants request clarification of the statutory basis of the rejection.

Applicants also submit that the claims are definite irrespective of the recitation of a step of taking a sample of body fluid. According to the MPEP, a claim is definite where the claim defines the subject matter with a reasonable degree of particularity and distinctness.[7] In evaluating a claim for compliance with this requirement, the Examiner must consider the claim as a whole to determine "whether the claim apprises one of ordinary skill in the art of its scope."[8]

In the present case, the skilled artisan reading the pending claims would be apprised of their scope. The claims recite, *inter alia*, an immunassay method comprising (a) contacting a "body fluid" with a composition comprising a specified polypeptide and (b) detecting whether immunospecific binding has occurred between the polypeptide and an antibody component of the body fluid. It would be clear to the skilled artisan that a sample of

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[4] See MPEP § 2172.01.
[5] *See id.*
[6] *Id.*
[7] *See, e.g.*, MPEP § 2173.02.
[8] *Id.* (citing cases).

body fluid is taken at some time before the recited steps. It is not "essential," however, that the practitioner of the method be the one to "take" the body fluid (*e.g.*, from a subject). Indeed, in normal practice of immunoassay methods, samples of body fluid to be used in such methods have already been separately taken and made available to a practitioner of the immunoassay. Accordingly, the steps as recited in (a) and (b) are sufficient to reasonably apprise one of skill in the art as to what constitutes an infringement of the method. For these reasons, Applicants again request reconsideration of the present rejection.

Should the Examiner maintain the present rejection, and while Applicants do not agree with the Examiner for the reasons above, independent claims 1 and 12 have been amended to recite the step of "providing a body fluid" in order to further expedite prosecution of the instant application. Support for this amendment is found in the specification as filed at, for example, Example 2 (describing one embodiment in which body fluid samples are provided into wells for carrying out an immunoassay in accordance with the present invention). For reasons substantially as set forth above, Applicants believe that the step of "providing" a body fluid is implicit in the claims as previously presented. Accordingly, Applicants believe the present amendments do not narrow the scope of the claims.

In view of the amendments and remarks above, Applicants believe claims 1-12 to be definite under 35 U.S.C. § 112, second paragraph. Withdrawal of the rejection is respectfully requested.

Claim 6

The Examiner continues to reject claim 6 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for reciting that the polypeptide "retains substantially all of the immunological reactivity of the unmodified polypeptide." For the reasons set forth below, Applicants maintain traversal of the instant rejection.

First, the Examiner contends that the specification's teachings (that relate to the claimed polypeptide's ability to "immunologically mimic" an epitope of the HIV pol region) "do not overcome the lack of clarity presented by the phrase 'substantially all.'" The Examiner states the following:

> the term "immunologically mimics" "merely indicates that a substance simulates the immunological properties of another ligand. Thus, if a substance retains "substantially," but not "all" of the antigenic properties of a ligand, the substance does not "mimic" the ligand.[9]

In response, in addition to a lack of any evidentiary support for the Examiner's interpretation of "immunologically mimic," the Examiner's interpretation is not consistent with the specification's teachings. Under the Examiner's interpretation, a polypeptide does not "immunologically" mimic an antigen unless it retains absolutely "all" of its antigenic properties. It is well-established, however, that interpretation of the claims during examination must be consistent with the interpretation that those skilled in the art would reach based on the application's disclosure.[10] Here, the specification states, for example, that in certain situations where regions of HIV are structurally polymorphic, "it may be desirable to vary one or more particular amino acids to ***more*** effectively mimic the differing epitopes of the different retroviral strains." (Substitute Specification at page 4, lines 14-17 (emphasis provided).) Thus, the specification clearly contemplates that "immunological mimicry" does not necessarily require absolute effectiveness with respect to simulation of antigenic properties.

The Examiner further states the following:

> [T]he specification fails to provide any endpoints (i.e. data) that would allow one skilled in the art to define a range of activity that 'substantially all' refers to. For example, there is no teaching of the binding affinities of the polypeptides that resemble "substantially all" of the immunological reactivity of the unmodified polypeptide.[11]

In response, whether the specification explicitly discloses "endpoints" that define a range corresponding to "substantially all" is not determinative as to whether a claim is definite. Even assuming (for argument's sake only) that the specification itself provides no express

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[9] Office Action dated June 15, 2005, at page 10.
[10] *See, e.g., In re Cortright*, 165 F.3d 1353, 1359, 49 USPQ2d 1464, 1468 (Fed. Cir. 1999). MPEP § 2111.
[11] Office Action dated June 15, 2005, at page 10.

standard for "substantially all," a claim reciting such terminology is still definite where one of ordinary skill in the art "would be nevertheless reasonably apprised of the scope of the invention."[12] Here, as of the effective filing date of the instant application, the term "substantially," with reference to preservation of a polypeptide's immunological reactivity, was commonly used in the art of immunological assays and, therefore, would have a defined meaning to the skilled artisan. Accordingly, the skilled artisan would be reasonably apprised of the scope of the phrase "substantially all of the immunological reactivity of the unmodified polypeptide" in claim 6.

As evidence of the accepted usage (and thus definiteness) of the term "substantially" in the immunoassay art, Applicants respectfully refer the Examiner to the patent literature in the field. Exemplary patent references using the term "substantially" to define a range of immunoreactivity include, for example, U.S. Patent Nos. 5,777,074; 5,151,266; 5,106,726; and 4,879,212. In each case of the above-referenced patents, the claims characterize immunoreactivity of a composition using the term "substantially." In each case, the corresponding specification neither expressly defines the meaning of "substantially" nor provides "endpoints" that would define a range corresponding to "substantially."

For the Examiner's convenience, set forth hereinbelow, from each of the above-referenced patents, is language from a claim using the term "substantially" in the context of the immunoassay art.

U.S. Patent No. 5,777,074:

> [A]nalogues therefore wherein the amino acids in the sequence are substituted ***as long as the immunoreactivity with antibodies to HIV-1 gp41*** derived from the three dimensional conformation of the sequences ***is substantially preserved*** ....[13]

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[12] MPEP § 2173.05(b).
[13] U.S. Patent No. 5,777,074 at claim 20 (empasis provided).

U.S. Patent No. 5,151,266:

> A method for increasing the solubility of an immunoreactive immunoconjugate preparation ***without substantially affecting the immunoreactivity of the preparation*** ....[14]

U.S. Patent No. 5,106,726:

> [A]n analogue of one of the above peptides having an amino acid sequence derived from a strain/isolate of HCV in a region corresponding to the peptide and ***having specific immunoreactivity*** to antibodies to HCV relative to the peptide ***that is substantially preserved*** ....[15]

U.S. Patent No. 4,879,212:

> [O]r analogues thereof, as long as the ***immunoreactivity to antibodies to HTLV-III*** derived from the three dimensional conformation ***is preserved substantially***.[16]

Thus, as of the effective filing of the instant application, those of ordinary skill in the art accepted the usage of "substantially" in reference to immunoreactivity of immunological compositions, and the U.S. Patent Office accepted such terminology as reasonably apprising the ordinarily skilled artisan of the scope of such compositions. Therefore, Applicants submit that the phrase "substantially all of the immunological reactivity of the unmodified polypeptide," as recited in claim 6 of the instant application, reasonably apprises the skilled artisan of the scope of the claim and is thus definite under 35 U.S.C. § 112, second paragraph. In view of the above, withdrawal of the present rejection is respectfully requested.

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[14] U.S. Patent No. 5,151,266 at, *e.g.*, claim 1(emphasis provided).
[15] U.S. Patent No. 5,106,726 at, *e.g.*, claim 1 (emphasis provided).
[16] U.S. Patent No. 4,879,212 at, *e.g.*, claim 1 (emphasis provided).

**Rejections under 35 U.S.C. § 112, first paragraph**

Claim 6 stands rejected under 35 U.S.C. § 112, first paragraph, as allegedly not enabled by the specification for the recited deletion of amino acid residues "that enable the modified protein to retain its immunological activity." Claim 6 also stands rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking written description for these conservative deletions.

While Applicants do not agree with these rejections or reasons for rejection, but in order to further expedite prosecution of the instant application, claim 6 has been amended to delete reference to "deletion" of amino acid residues. In view of this amendment, Applicants believe the present rejections of claim 6 to be obviated. Withdrawal of the rejections is respectfully requested.

**Rejections under 35 U.S.C. § 103**

Zaitsev in view of Montagnier

Claims 1-12 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Zaitsev *et al.* (RU 2043411 C1) in view of Montagnier *et al.* (U.S. 5,221,610). The Examiner asserts that Zaitsev *et al.* "disclose a composition for detecting antibodies to HIV-1 and HIV-2, wherein the composition comprises a polypeptide consisting essentially of the amino acid sequence of SEQ ID NO:3." The Examiner further contends that the different immunoassay formats of Mantagnier et al. are "a matter of choice to one skilled in the art," and that the skilled artisan would thus be "motivated to apply Zaitsev et al.'s polypeptides to the immunoassays taught by Montagnier et al."

While Applicants do not agree with the rejection or reasons for rejection, but in order to further expedite prosecution of the instant application, independent claims 1 and 12 have been amended to recite "... at least one polypeptide ~~consisting essentially of~~ no more than 60 amino acid residues in length and having [the polypeptide sequence of SEQ ID NO:3] ...." Support for this amendment is found in the substitute specification at page 2, lines 8-11.

A *prima facie* case of obviousness under 35 U.S.C. § 103 requires, *inter alia*, a teaching or suggestion of each and every claim limitation in the cited reference (or references when combined). MPEP §§ 2143, 2143.03. Here, neither Zaitsev nor Montagnier teach or suggest a polypeptide of no more than 60 amino acid residues in length and having the sequence set forth in SEQ ID NO:3. Accordingly, for at least this reason, claims 1-12 are patentable over Zaitsev in view of Montagnier. Withdrawal of the rejection is respectfully requested.

Suckhanova in view of Montagnier

Claims 1-4 and 6-12 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Suckhanova *et al.* (RU 2085586 C1) in view of Montagnier *et al.* (US 5,221,610). The Examiner states that Sukhanova "discloses a polypeptide consisting essentially of SEQ ID NO:3" and that this polypeptide "may be used in the diagnosis of HIV." The Examiner also asserts that it would have been obvious to the skilled artisan to apply Sukhanova et al.'s polypeptide to the immunassays disclosed in Montagnier et al."

While not agreeing with the rejection or reasons for rejection, Applicants believe this rejection to be obviated by the present amendments set forth above in response to the rejection in view of Zaitsev and Montagnier. In particular, the claims now require that the polypeptide, having SEQ ID NO:3, be "no more than 60 amino acid residues in length." Neither Suckhanova nor Montagnier teach or suggest a polypeptide of no more than 60 amino acid residues in length and having the sequence set forth in SEQ ID NO:3. Accordingly, for at least this reason, claims 1-4 and 6-12 are patentable over Suckhanova in view of Montagnier. Withdrawal of the rejection is respectfully requested.

## CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 206-467-9600.

Respectfully submitted,

Dated: November 28, 2005

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